State agencies or private, nonprofit entities as accrediting bodies to implement certification and quality assurance programs in accordance with the requirements of these sections. The delegation excludes the authority to submit reports to the Congress.

[57 FR 43398, Sept. 21, 1992]

§5.66 Approval of schools providing food-processing instruction.

The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs under §113.10 of this chapter regarding the approval of schools giving instruction in retort operations, processing systems operations, aseptic processing and packaging system operations, and container closure inspections:

(a) The Director and Deputy Directors, Center for Food Safety and Applied Nutrition (CFSAN).

(b) The Director, Office of Policy, Planning, and Strategic Initiatives, CFSAN.

(c) The Director, Office of Plant and Dairy Foods and Beverages, CFSAN.

[59 FR 42492, Aug. 18, 1994]

§5.67 Issuance of notices of opportunity for a hearing on proposals for denial of approval of applications for licenses or revocation of licenses and certain notices of revocation of licenses.

The Director and Deputy Director, Center for Biologics Evaluation and Research are authorized to issue:

(a) Notices of opportunity for a hearing on proposals to deny approval or filing of applications for establishment or product licenses under §601.4(b) of this chapter.

(b) Notices of opportunity for a hearing on proposals to revoke establishment or product licenses under §601.5(b) of this chapter.

(c) Notices of revocation, at the manufacturer's request, of establishment or product licenses under §§601.5(a) and 601.8 of this chapter.

(d) Notices of revocation when the manufacturer has waived the opportunity for hearing under §601.7(a) of this chapter.

[50 FR 30697, July 29, 1985, as amended at 54 FR 8318, Feb. 28, 1989; 56 FR 25025, June 3, 1991]

§5.68 Issuance and revocation of licenses for the propagation or manufacture and preparation of biological products.

The following officials are authorized to issue licenses under section 351 of the Public Health Service Act (42 U.S.C. 262) for the propagation or manufacture and preparation of biological products as specified in the act, and to revoke such licenses at the manufacturer's request:

(a) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER).

(b) The Director and Deputy Director, Office of Biological Product Review, CBER.

[49 FR 14934, Apr. 16, 1984, as amended at 54 FR 8318, Feb. 28, 1989]

§5.69 Notification of release for distribution of biological products.

The following officials are authorized to issue written notices of release for distribution of licensed biological products under subchapter F (parts 600 through 699) of this chapter:

(a) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER).

(b) The Director and Deputy Director, Office of Biological Product Review, CBER.

(c) The Director and Deputy Director, Division of Product Quality Control, Office of Biological Product Review, CBER.

[49 FR 14934, Apr. 16, 1984, as amended at 50 FR 19341, May 8, 1985; 54 FR 8318, Feb. 28, 1989]

§5.70 Issuance of notice implementing the provisions of the Drug Amendments of 1962.

The Director, Deputy Center Director for Review Management, and Deputy Director, Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER), are authorized to issue notices and amendments thereto implementing section 107(c)(3) of the Drug Amendments of 1962 (Pub. L. 87–781) by announcing new or revised efficacy findings on human drugs that are or were subject to the

provisions of sections 505 and 507 of the Federal Food, Drug, and Cosmetic Act.

[62 FR 2556, Jan. 17, 1997]

§ 5.71 Termination of exemptions for new drugs for investigational use in human beings and in animals.

(a) The following officials, for drugs under their jurisdiction, are authorized to perform all the functions of the Commissioner of Food and Drugs on the termination of exemptions for new drugs (including those that are biological products which are subject to the licensing provisions of the Public Health Service Act) for investigational use in human beings under §312.44 of this chapter and in animals under §312.160 of this chapter:

(1) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER).

(2) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(b) The following officials, for drugs under their jurisdiction, are authorized to terminate exemptions for new drugs for investigational use when sponsors fail to submit an annual progress report under §312.44(b)(1)(viii) of this chapter:

(1) The Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

(2) The Directors and Deputy Directors of the divisions in the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

(3) The Director and Deputy Director, Office of Biological Product Review, CBER.

(4) The Director and Deputy Director, Division of Biological Investigational New Drugs, Office of Biological Product Review.

(c) The following officials, for drugs under their jurisdiction, are authorized to make the findings set forth in §312.44(b) of this chapter and to notify sponsors and invite correction before termination action on such exemptions:

(1) The Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

(2) The Directors and Deputy Directors of the divisions in the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

(3) The Director and Deputy Director, Office of Biological Product Review, CBER.

(4) The Director and Deputy Director, Division of Biological Investigational New Drugs, Office of Biological Product Review.

(d) The following officials are authorized to perform all functions of the Commissioner of Food and Drugs with regard to the termination of new animal drugs for investigational use in animals under §511.1 of this chapter:

(1) The Director and Deputy Director, Center for Veterinary Medicine (CVM).

(2) The Director and Deputy Director, Office of New Animal Drug Evaluation, CVM.

[49 FR 14934, Apr. 16, 1984, as amended at 50 FR 14094, Apr. 10, 1985; 52 FR 7829, Mar. 13, 1987; 54 FR 8318, Feb. 28, 1989; 55 FR 51688, Dec. 17, 1990; 62 FR 2556, Jan. 17, 1997]

§ 5.72 Authority to approve and to withdraw approval of a charge for investigational new drugs.

The following officials, for drugs under their jurisdiction, are authorized to perform all the functions of the Commissioner of Food and Drugs to approve a charge and to withdraw approval to charge for investigational drugs in a clinical trial under an investigational new drug application under §312.7(d)(1) of this chapter:

(a) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(b) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER).

[55 FR 5445, Feb. 15, 1990, as amended at 62 FR 2556, Jan. 17, 1997]

§ 5.73 Certification of insulin.

The following officials are authorized to certify or reject batches of drugs containing insulin pursuant to section 506(a) of the Federal Food, Drug, and Cosmetic Act:

(a) The Director, Deputy Center Director for Review Management, and